IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF MISSISSIPPI
GREENVILLE DIVISION

Linda Lary and Lacy Lary individually and by and on behalf of the Wrongful Death Beneficiaries of Michael Lary

Plaintiff,

v.

PURDUE PHARMA, L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY; CEPHALON, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; ALLERGAN PLC f/k/a ACTAVIS, PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES; INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINKRODT PLC; MALLINKRODT LLC; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; MCKESSON CORPORATION; and DOES 1 – 100, INCLUSIVE

Defendants.

CIVIL ACTION NO. 4:19-CV-189-DMB-JMV

COMPLAINT

Complaint for Wrongful Death Fraud; Negligence; Negligence *Per Se*; Civil Conspiracy; Unjust Enrichment; and Violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, et seq.

JURY TRIAL DEMANDED

PLAINTIFF'S ORIGINAL COMPLAINT

Plaintiffs, Linda Lary and Lacy Lary individually and on behalf of the wrongful death beneficiaries of Michael Lary by and through undersigned counsel files this Complaint against Defendants Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Inc., Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Johnson & Johnson, Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc. n/k/a Janssen Pharmaceuticals Inc., Janssen Pharmaceutica, Inc.n/k/a Janssen Pharmaceuticals, Inc., Noramco, Inc., Endo Health Solutions Inc., Endo Pharmaceuticals Inc., Allergan PLC f/k/a Actavis PLC, Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., Watson Laboratories, Inc., Actavis, LLC, Actavis Pharma, Inc. f/k/a/ Watson Pharma, Inc., Mallinckrodt Plc, Mallinckrodt LLC, ("Manufacturer Defendants"), AmerisourceBergen Drug Corporation, Cardinal Health, Inc., McKesson Corporation ("Distributor Defendants"), and Does 1 – 100, inclusive. (collectively "Defendants").

INTRODUCTION

1. Mississippi is facing an unprecedented opioid addiction epidemic. Data shows that it is the fourth highest prescriber of opioids in the country.[1] Mississippi's opioid overdose death numbers show a 79 percent increase from 2016 to 2017.[2] From 2011-2014, prescriptions for oxycodone increased in Mississippi by 33%, while prescriptions for morphine and fentanyl increased by 17% and 15.2%, respectively.[3] According to the State Bureau of Narcotics Director John Dowdy, "Mississippi is emerging on the brink of a super pandemic."[4]

[1] CDC Annual Surveillance Report of Drug-Related Risks and Outcomes.
[2] http://www.clarionledger.com/story/news/local/2018/02/22/ohio-leads-county-opioid-overdoses-but-what- do-we-do-when-were-like-ohio/330676002/
[3] "The Mississippi Opioid Epidemic: Data Brief," Mississippi State Dept. of Health, http://msdh.ms.gov/msdhsite/_static/resources/7292.pdf
[4] www.clarionledger.com/story/news/2017/06/11/drug-overdose-deaths-reach-record-mississippi/349433001/

2. In 2016 alone, health care providers wrote more than 289 million prescriptions for opioids, enough for *every adult in the United States* to have more than one bottle of pills.[5] In that same year, there were 3,574,662 prescriptions written and 201,224,298 dosage units dispensed for opioids in Mississippi. That equals to roughly 70 pills for every man, woman and child in Mississippi.

3. The is located in Hinds County, Mississippi, which has an opioid prescribing rate of 72.2 prescriptions for every 100 residents of the county in 2016 – higher than the national average.[6] The , Mississippi's Capital city, has the largest population of citizens, and has had a significantly high number of drug related deaths.[7]

4. Unfortunately, using opioids too often leads to misusing and abusing opioids. In 2014, almost 2 million Americans abused or were addicted to opioids.[8] That same year, more people died from drug overdoses than in any other year, and most overdose deaths involved an opioid.

5. In fact, accidental drug overdose deaths, of which at least two-thirds are opioid overdoses, are the leading cause of death for Americans under the age of 50. Accidental drug overdose deaths, predominantly from opioids, exceed the number of deaths caused by cars or guns.

6. The economic burden caused by opioid abuse in the United States is approximately $78.5 billion, including lost productivity and increased social services, health insurance costs, increased criminal justice presence and strain on judicial resources, and substance abuse treatment and rehabilitation.[9]

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[5] *Prevalence of Opioid Misuse*, BupPractice, https://www.buppractice.com/node/15576 (Sept. 7, 2017).
[6] https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html
[7] http://opioid.amfar.org/MS#data-explorer
[8] Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, 2014.
[9] CDC Foundation's New Business Pulse Focuses on Opioid Overdose Epidemic, Centers for Disease Control and Prevention (Mar. 15, 2017), https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html.

7. This epidemic did not occur by chance. Defendants manufacture, market, distribute, and sell prescription opioids, including, but not limited to, brand-name drugs like OxyContin, Vicodin, Opana, Percocet, Percodan, Roxicodone, Avinza, and generics like oxymorphone and hydrocodone, which are powerful narcotic painkillers. Other Defendants manufacture, market, distribute, and sell prescription opioids, including, but not limited to, brand-name drugs like Fentanyl, Fentora, Duragesic, Ultram, and Ultracet.

8. Historically, opioids were considered too addictive and debilitating for treating chronic pain,[10] such as back pain, migraines, and arthritis, and were used only to treat short-term acute pain or for palliative or end-of-life care.

9. By the late 1990s or early 2000s, however, each Defendant began a marketing scheme to persuade doctors and patients that opioids can and should be used for chronic pain. Each Defendant spent, and continues to spend, millions of dollars to promote the benefits of opioids for chronic pain while trivializing or even denying their risks.

10. Contrary to the language of their drugs' labels, Defendants falsely and misleadingly: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" thereby advocating that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction.

11. Defendants distributed these falsehoods through their sales representatives and physicians who supported Defendants' message. Sales representatives, working at Defendants'

[10] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

behest, promoted highly addictive opioids through souvenirs and toys, including but not limited to, opioid brand-bearing stuffed plush toys, dolls, coffee cups, fanny packs, water bottles, notepads, pens, refrigerator magnets, clocks, letter openers, rulers, daytime planners, bags, puzzles, posters, clipboards, highlighters, flashlights, key chains, clothing, reflex mallets, and mock-ups of the Unites States Constitution.

12. Defendants also used third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "FrontGroups").

13. Defendants worked with KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. After their individual and concerted efforts, Defendants convinced doctors that instead of being addictive and unsafe for long-term use in most circumstances, opioids were *required* in the compassionate treatment of chronic pain.

14. The Distributor Defendants were not standing by idly while the Marketing Defendants were peddling their opioids to physicians and consumers. Cardinal, AmerisourceBergen, and McKesson ("Distributor Defendants") are three of the largest opioid distributors in the United States. Distributor Defendants purchased opioids from Defendants herein and sold them to pharmacies throughout the .

15. Despite the alarming and suspicious rise in the ordering of opioids by retailers in Mississippi, Distributor Defendants did nothing.

16. Essentially each Defendant ignored science and consumer health for profits.

Defendants' efforts were so successful that opioids are now the most prescribed class of drugs generating $11 billion in revenue for drug companies in 2014 alone.

17. As a direct and foreseeable consequence of Defendants' misrepresentations regarding the safety and efficacy of using opioids Michael Lary was prescribed opioids, became addicted and ultimately died as a result of his addiction. Linda Lacy brings these claims for herself individually and on behalf of the wrongful death beneficiaries of Michael Lary for all damages available under the law for wrongful death and negligence and the other causes of action in this complaint.

VENUE AND JURISDICTION

18. This Court has federal subject-matter jurisdiction under 28 U.S.C.A. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000, exclusive of interest and costs.

19. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has personal jurisdiction over the Defendants as they individually and collectively engaged in systematic and continuous contacts with Mississippi sufficient to establish jurisdiction over each Defendant. Likewise, this District has personal jurisdiction over Defendants because they conduct business in Mississippi, purposefully direct or directed their actions toward Mississippi, consented to be sued in Mississippi by registering an agent for service of process, consensually submitted to the jurisdiction of Mississippi when obtaining a distributor license, and have the requisite minimum contacts with Mississippi necessary to constitutionally permit the Court to exercise jurisdiction. This Court also has personal jurisdiction over the Defendants as each Defendant cause and/or contributed to a public nuisance and a drug related nuisance, as further alleged herein, that continues to exist in Mississippi.

20. Venue is further proper in the federal judicial district pursuant to 28 U.S.C.A. § 1391 and 18 U.S.C.A. § 1965 because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C.A. §§ 1391(b); § 1965(a).

PARTIES

A. Plaintiffs

21. Plaintiffs, Linda Lary and Lacy Lary by and for the wrongful death beneficiaries of Michael Lary are a citizens of Carroll County, Mississippi residing at 826 County Road 185; Greenwood, MS 38930.

22. Plaintiffs have standing to bring all claims pled herein and to recover damages incurred as a result of Defendants' actions and omissions.

B. Defendants

Manufacturer Defendants

23. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware.

24. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut.

25. THE PURDUE FREDERICK COMPANY, INC. is a Delaware corporation with its principal place of business in Stamford, Connecticut.

26. The Purdue Defendants (collectively "Purdue") manufacture, promote, sell, and distribute opioids in the U.S. and the . Purdue's opioid drug, OxyContin, is among the most addictive and abused prescription drugs in the history of America. Since 2009, Purdue's annual

nationwide sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

27. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids in the U.S. and in the .

28. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc.

29. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011.

30. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in the , discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in the , indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently

display Teva Ltd.'s logo. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.")

31. JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

32. NORAMCO, INC. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016.

33. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J).

34. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

35. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to as "Janssen.")

36. Janssen manufactures, promotes, sells, and distributes opioids in the U.S. and in the

, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sols the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

37. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

38. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.")

39. Endo develops, markets, and sells opioid drugs in the U.S. and in the . Endo also manufactures and sells generic opioids in the U.S. and the .

40. ALLERGAN PLC formerly known as Actavis PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, Defendant, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to ACTAVIS, INC., then to ACTAVIS PLC in October 2013.

41. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

42. ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC.

43. ACTAVIS LLC is a Delaware limited liability company with its principal place of

business in Parsippany, New Jersey.

44. Upon information and belief, ALLERGAN PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.").

45. Actavis manufactures, promotes, sells, and distributes opioids in the U.S. and in the , including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. Actavis aquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

46. MALLINCKRODT, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. MALLINCKRODT, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, plc. Mallinckrodt, plc and Mallinckrodt, LLC are referred to as "Mallinckrodt."

Distributor Defendants

47. MCKESSON CORPORATION ("McKesson") is a Delaware corporation with its principal place of business in San Francisco, California. McKesson distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including Mississippi and the . Upon information and belief, McKesson is a pharmaceutical distributor licensed to do business in Mississippi.

48. CARDINAL HEALTH, INC. ("Cardinal") is an Ohio Corporation with its principal place of business in Dublin, Ohio. Cardinal distributes pharmaceuticals to retail pharmacies and

institutional providers to customers in all 50 states, including Mississippi and the . Cardinal does substantial business in Mississippi and, upon information and belief, Cardinal is a pharmaceutical distributor licensed to do business in Mississippi.

49. AMERISOURCEBERGEN DRUG CORPORATION ("Amerisource") is a Delaware Corporation with its principal place of business in Chesterbrook, Pennsylvania. Amerisource distributes pharmaceuticals to retail pharmacies and institutional providers to customers in all 50 states, including Mississippi and the . Amerisource does substantial business in Mississippi and, upon information and belief, Amerisource is a pharmaceutical distributor licensed to do business in Mississippi.

50. The City lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of Defendants sued herein under the fictitious names DOES 1 through 100 inclusive. The City will amend this Complaint to show their true names and capacities if and when they are ascertained. The is informed and believes, and on such information and belief alleges, that each of the Defendants named as a DOE has engaged in conduct that contributed to cause events and occurrences alleged in this Complaint and, as such, shares liability for at least some part of the relief sought herein.

FACTUAL ALLEGATIONS

51. Before the 1990s, generally accepted standards of medical practice dictated that opioids should be used only for short-term acute pain – pain relating to recovery from surgery or for cancer or palliative (end-of-life) care. Using opioids for chronic pain was discouraged or even prohibited because there was a lack of evidence that opioid improved patients' ability to overcome pain and function. Instead the evidence demonstrated that patients developed tolerance to opioids over time, which increased the risk of addiction and other side effects.

52. Defendants dramatically changed doctors' views regarding opioids through a well-funded deceptive marketing scheme. Each Defendant used direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use.

A. Defendants Used Multiple Avenues to Disseminate Their False and Deceptive Statements about Opioids.

53. Defendants spread their false and deceptive statements by (1) marketing their branded opioids directly to doctors and patients in the and (2) deploying so- called unbiased and independent third parties to the .

1. Defendants Spread and Continue to Spread Their False and Deceptive Statements Through Direct Marketing of Their Branded Opioids.

54. Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted advertising campaigns touting the purported benefits of their branded drugs. For example, Defendants spent more than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001, including $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

55. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website, www.opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like a construction worker and chef, implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Pursuant to a settlement agreement, Endo and Purdue agreed in late 2015 and 2016 to

halt these misleading representations in New York, but they may continue to disseminate them in Mississippi.

56. Additionally, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Defendants devoted massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing branded opioids to doctors, including $108 million by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis. This amount is twice as much as Defendants spent on detailing in 2000.

57. Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

58. Defendants employed the same marketing plans, strategies, and messages in the , Mississippi as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels and in each sales territory. Defendants consider this high level

of coordination and uniformity crucial to successfully marketing their drugs.

2. Defendants Used a Diverse Group of Seemingly Independent Third Parties to Spread False and Deceptive Statements about the Risks and Benefits of Opioids.

59. Defendants also deceptively marketed opioids in the through unbranded advertising – *i.e.*, advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for treating chronic pain.

60. Unbranded advertising also avoided regulatory scrutiny because Defendants did not have to submit it to the FDA, and therefore it was not reviewed by the FDA.

61. Defendants' deceptive unbranded marketing often contradicted their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER.

Opana ER Advertisement **(Branded)**	**Pain: Opioid Therapy** **(Unbranded)**
"All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use**."	"People who take opioids **as prescribed usually do not become addicted**."

a. Key Opinion Leaders (KOLs)

62. Defendants spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported using

opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

63. Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. KOLs' professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Defendants.

64. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Defendants created opportunities for KOLs to participate in research studies Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

65. Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage using opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Defendants were able to direct and exert control over each of these activities through their KOLs.

66. Pro-opioid doctors are one of the most important avenues that Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy.

67. Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

1. Russell Portenoy

68. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL who Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

69. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS")/American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants.

70. Dr. Portenoy also made frequent media appearances promoting opioids. He appeared on *Good Morning America* in 2010 to discuss using opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Mississippi and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."[11]

71. Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[12] These lectures falsely claimed that less than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed

[11] Good Morning America television broadcast, ABC News (Aug. 30, 2010).
[12] Thomas Catan & Evan Perez, A Pain-Drug Champion Has Second Thoughts, WALL ST. J., Dec. 17, 2012.

over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist."[13] Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well…I guess I did."[14]

2. Lynn Webster

72. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake County, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster authored numerous CMEs sponsored by Cephalon, Endo, and Purdue while he was receiving significant funding from Defendants (including nearly $2 million from Cephalon).

73. In 2011, Dr. Webster presented a program via webinar sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended using risk screening tools, such as urine testing and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths," which was available to and was intended to reach the City's doctors.

74. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo

[13] *Id.*
[14] *Id.*

distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[15]

b. Front Groups

75. Defendants entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for treating chronic pain. Under Defendants' direction and control, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit prescribing opioids in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

76. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure these Groups would generate only the messages Defendants wanted to distribute. Even so, the Front Groups held themselves out as independent and as serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

77. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

[15]John Fauber & Ellen Gabler, Networking Fuels Painkiller Boom, MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012).

1. American Pain Foundation ("APF")

78. The most prominent of Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next at $1.7 million.

79. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

80. PF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also engaged in a significant multimedia campaign – through radio, television, and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach patients and consumers in the .

2. American Academy of Pain Medicine ("AAPM")

81. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Defendants' deceptive marketing of chronic opioid therapy.

82. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers.

AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, Cephalon, and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

83. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[16]

84. AAPM's staff understood they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

85. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic

[16]Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), http://www.medscape.org/viewarticle/500829.

pain and claimed there was a low risk that patients would become addicted to opioids. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it still lingers on the internet elsewhere.

86. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend using opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

87. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because he was concerned the 2009 Guidelines were influenced by contributions that drug companies, including Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in the during the relevant time period, are still available online, and were reprinted in the *Journal of Pain*.

B. Defendants' Marketing Scheme Misrepresented the Risks and Benefits of Opioids.

88. To convince doctors and patients that opioids can and should be used to treat chronic pain, Defendants had to convince them that long-term opioid use is both safe and effective.

Knowing they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made claims that were not supported by, or were contrary to, the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

C. Defendants Falsely Trivialized or Failed to Disclose the Known Risks of Long- Term Opioid Use.

89. To convince doctors and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations; they continue to make them today.

90. ***First***, Defendants falsely claimed the risk of addiction is low and unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. For example:

a. Actavis's predecessor caused a patient education brochure to be distributed

in 2007 claiming opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond;

b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online;

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them;"

d. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com;

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain;"

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated;"

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management* – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction." This publication is still available online; and

h. Detailers for Purdue, Endo, Janssen, and Cephalon in The City of Jackson minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for opioid abuse with purportedly abuse- deterrent formulations; and routinely did not correct the misrepresentations noted above.

91. These claims contradict longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is

"extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])."[17] The guideline points out that "[o]pioid pain medication use presents serious risks, including…opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."[18]

92. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA discussed the risks related to opioid use and that IR opioids are associated with "persistent abuse, addiction, overdose mortality, and risk of NOWS [neonatal opioid withdrawal syndrome]."[19]

93. According to the FDA, because of the risks associated with long-term opioid use, including "the serious risk of addiction, abuse, misuse, overdose, and death,"[20] opioids should be "reserved for pain severe enough to require opioid treatment and for which alternative treatment options (e.g., non-opioid analgesics or opioid combination products, as appropriate) are inadequate or not tolerated."[21]

94. The warnings on Defendants' own FDA-approved drug labels caution that opioids "exposes users to risks of addiction, abuse and misuse, which can lead to overdose and death"[22] and that addiction "can occur in patients appropriately prescribed"[23] opioids.

95. ***Second***, Defendants falsely instructed doctors and patients that signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Defendants

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[17] *CDC Guideline for Prescribing Opioids for Chronic Pain – United States 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016)
[18] *Id.*
[19] *FDA Announcement of Enhanced Warnings for Immediate-Release Opioid Pain Medications Related to Risks of Misuse, Abuse, Addiction, Overdose and Death*, Federal Drug Administration (Mar. 22, 2016)
[20] *Id.*
[21] *Id.*
[22] *See, e.g.*, OxyContin label and insert at OxyContin.com
[23] *Id.*

called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and claimed that pseudoaddiction is substantiated by scientific evidence. For example:

a. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition continues to teach that pseudoaddiction is real;

b. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management;"

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials;

d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated;" and

e. Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse*. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long- acting opioid.

96. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful

pain relief early in treatment…are unlikely to experience pain relief with longer-term use,"[24] and that physicians should "reassess pain and function within 1 month"[25] in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids"[26] because the patient is "not receiving a clear benefit."[27]

97. ***Third,*** Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher- risk patients. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting opioid therapy for chronic pain. For example:

a. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts;

a. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths;" and

b. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

98. Once again, the 2016 CDC Guideline confirms these representations are false.

[24] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra*.
[25] *Id.*
[26] *Id.*
[27] *Id.*

The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts, widely believed by doctors to detect and deter abuse, "for improving outcomes related to overdose, addiction, abuse, or misuse."[28] As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse"[29] and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[30]

99. ***Fourth***, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem thereby failing to disclose the increased difficulty of stopping opioids after long-term use.

100. For example, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation."

101. Defendants deceptively minimized the significant symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid

[28] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[29] *Id.*
[30] *Id.*

use.

102. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be limited to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms,"[31] because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days."[32] The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence"[33] and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal"[34] and pausing and restarting tapers depending on the patient's response.

103. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."[35]

104. ***Fifth***, Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. For example:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to

[31] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

Kadian, Actavis continued to use these materials in 2009 and beyond;

b. Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online;

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain;"

d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief;"

e. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages;

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will;

g. Purdue sponsored APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online;

h. Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages; and

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

105. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic

pain are not established"[36] while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."[37]

106. More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."[38] Similarly, there is an "increased risk for opioid use disorder, respiratory depression, and death at higher dosages."[39] That is why the CDC advises doctors to avoid increasing dosages above 90 morphine milligram equivalents per day.

107. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged that available data suggested that increasing the opioid dosage likewise increased certain adverse events. For example, the FDA noted that studies suggest a positive association between high-dose opioid use and overdoses.

108. ***Finally***, Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse.

109. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant in a way that suggested it was more difficult to abuse. This claim was false.

110. The FDA warned in a 2013 letter that there was no evidence Endo's design would provide a reduction in oral, intranasal or intravenous abuse.[40] Moreover, Endo's own studies,

[36] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *See FDA Statement: Original Opana ER Relisting Determination* (May 10, 2013).

which it failed to disclose, showed that Opana ER could still be ground and chewed.

111. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was designed to be or is crush resistant. The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER.

112. Similarly, the 2016 CDC Guideline states that no studies support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse,"[41] noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[42]

113. These numerous, long-standing misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

D. Defendants Grossly Overstated the Benefits of Chronic Opioid Therapy.

114. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants had to persuade them that there was a significant benefit to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[43]

115. In fact, the CDC found no evidence showing "a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)"[44] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use.

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[41] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra.*

[42] *Id.*

[43] *Id.*

[44] *Id.*

116. In 2013, the FDA stated that it was unaware of any studies demonstrating the safety and efficacy of opioids for long-term use.[45] Despite this lack of studies, Defendants falsely and misleadingly touted the benefits of long-term opioid use and suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today. For example:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives;

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects;

c. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs;

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function;

e. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online;

f. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012;

g. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies,

[45] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Eval. & Res., to Andrew Kolodny, M.D., Pres. Physicians for Responsible Opioid Prescribing, Re Docket No. FDA-2012-P-0818 (Sept. 10, 2013).

that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site;

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast;

i. Janssen sponsored, funded, and edited a website, *Let's Talk Pain*, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube;

j. Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today;

k. Abbott's sales representatives were not only instructed to misrepresent the so-called benefits of OxyContin to doctors, such as it having a less euphoric effect than other opioids, but were being offered $20,000.00 cash prizes and luxury vacations for doing so; and

l. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

117. These claims find no support in the scientific literature. Most recently, the 2016 CDC Guideline, approved by the FDA, concluded, "There is no good evidence that opioids improve pain or function with long-term use"[46] and "complete relief of pain is unlikely."[47] (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

a. "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."[48]

[46] *CDC Guidelines for Prescribing Opioids for Chronic Pain, supra*
[47] *Id.*
[48] *Id.*

b. "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy;"[49] and

c. "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia." [50]

118. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations."[51] As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

119. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience…results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."[52]

120. Defendants also falsely emphasized or exaggerated the risks of competing products like NSAIDs so that doctors and patients would look to opioids first for treating chronic pain. Once again, Defendants' misrepresentations contravene pronouncements by and guidance from the FDA

[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), available at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesby FDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCcompanies/ucm259240.htm.

and CDC based on the scientific evidence.

121. Consequently, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should be used only as a last resort where alternative treatments like non-opioid drugs are inadequate. And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

122. In addition, Purdue misleadingly promoted OxyContin as unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action.

123. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. The reason is that OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. Although the patient experiences a powerful initial response, there is little or no pain relief at the end of the dosing period because less medicine is released.

124. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a substantial number of chronic pain patients taking OxyContin experience it.

125. This "end of dose" failure not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

126. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales

representatives continue to tell the City doctors that OxyContin lasts a full 12 hours.

E. Defendants also engaged in Other Unlawful, Unfair, and Fraudulent Misconduct.

127. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

128. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients.

129. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should be used only for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

130. Despite this advisory, Cephalon conducted and continues to conduct a well- funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer, or non-cancer, related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online;

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "*Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)*" to *Anesthesiology News*, *Clinical Oncology News*, and *Pain Medicine News* – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

131. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were safe and effective not only for treating chronic pain, but were also approved by the FDA for such uses.

132. Other Defendants herein participated in illicit and unlawful prescribing of its drugs. For example, Purdue did not report illegal prescribing of OxyContin until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets. In doing so, Purdue protected its own profits at the expense of public health and safety.

133. The State of New York also found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

F. Defendants Targeted Susceptible Prescribers and Vulnerable Patient Populations.

134. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including the . For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to

treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids.

135. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them.

136. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

G. Although Defendants Knew That Their Marketing of Opioids Was False and Deceptive, They Fraudulently Concealed Their Misconduct.

137. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes.

138. Not only did the FDA and other regulators warn Defendants, but Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear that harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming

numbers.

139. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

140. Moreover, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs.

141. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not.

142. Thus, Defendants successfully concealed from the medical community and patients' facts sufficient to arouse suspicion of the claims the now asserts. The City did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

H. By Increasing Opioid Prescriptions and Use, Defendants' Deceptive Marketing Scheme Has Fueled the Opioid Epidemic and Damaged the .

143. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies reveal that many doctors and patients are unaware of or do not understand the risks or benefits of opioids. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were

potentially addictive.[53]

144. Defendants' deceptive marketing scheme caused and continues to cause doctors in the to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids.

145. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

146. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

147. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly increase in opioid addiction, overdose, and death throughout the U.S. and the .

148. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that prescribing opioids has quadrupled since 1999, which has resulted in a parallel increase in opioid overdoses.[54] Indeed, there has been a

[53] Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities* (Jan. 27, 2016), *available at* http://www.hazeldenbettyford.org/about-us/news-and-media/pressrelease/doctors-missing-questions-that-could-prevent- opioid-addiction.

[54] CDC. National Vital Statistics System, Mortality. CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/; Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16

two-third increase in overdose deaths from using opioids since 2000.[55] For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the cycle of opioid pain medication misuse that contributes to the opioid overdose epidemic."[56]

149. Defendants' deceptive marketing scheme has also detrimentally impacted children in the . Overprescribing opioids for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household.

150. There was also an increase in the City's child protection services in the number of children in foster care driven by parental drug addiction. Children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive for cities like the .

151. Opioid addiction is one of the primary reasons that the residents seek substance abuse treatment. A significant number of admissions for drug abuse were associated with a primary diagnosis of opiate abuse or dependence.

152. Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed the 's communities. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused

December 2016.

[55] *National Vital Statistics System*, Mortality file and appearing *Center for Disease Control and Prevention* Morbidity and Mortality Weekly Report, January 1, 2006 / 64(50); 1378-82, Increases in Drug and Opioid Deaths – United States, 2000-2014.

[56] *CDC Guideline for Prescribing Opioids for Chronic Pain, supra; see also* Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. MMWR Morb Mortal Wkly Rep. ePub: 16 December 2016.

come, directly or indirectly, through doctors' prescriptions.[57]

153. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

154. The rise in opioid addiction caused by Defendants' deceptive marketing scheme has also resulted in an explosion in heroin use. For example, heroin use has more than doubled in the past decade among adults aged 18 to 25 years.[58] Moreover, heroin-related overdoses in the United States has more than quadrupled since 2010.[59]

155. The costs and consequences of opioid addiction are staggering. For example, in 2007, the cost of healthcare due to opioid abuse, dependence, and misuse was estimated at 25 billion, the cost of criminal justice was estimated at 5.1 billion, and the cost of lost workplace productivity was estimated at 25.6 billion.

156. Consequently, prescription opioid misuse, abuse, and overdose have an enormous impact on the health and safety of individuals, as well as communities at large, because the consequences of this epidemic reach far beyond the addicted individual.

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[57] Nathaniel P. Katz, *Prescription Opioid Abuse: Challenges and Opportunities for Payers*, Am. J. Managed Care (Apr. 19 2013), at 5 ("The most common source of abused [opioids] is, directly or indirectly, by prescription."), *available at* http://www.ajmc.com/publications/issue/2013/2013-1-vol19-n4/Prescription-Opioid-Abuse-Challenges-and-Opportunities-for-Payers.

[58] Centers for Disease Control and Prevention. Vital Signs: Today's Heroin Epidemic – More People at Risk, Multiple Drugs Abused. (http://www.cdc.gov/vitalsigns/heroin/index/html). MMWR 2015.

[59] https://www.cdc.gov/drugoverdose/data/heroin.html.

157. As a direct and foreseeable consequence of Defendants' wrongful conduct, Michael Lary became addicted to opioids and ultimately died as a result of his addiction. Plaintiffs seek all available damages under the law.

158. Defendants knew and should have known about these harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding.

159. Defendants also had access to and carefully watched government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. Defendants not only knew, but intended that their misrepresentations would persuade doctors to prescribe and encourage patients to use their opioids for chronic pain. Defendants' actions are neither permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by, and guidance from, the FDA based on the medical evidence and their own labels.

160. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also hijacked what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

I. Defendants' Fraudulent Marketing Has Led to Record Profits.

161. While using opioids has taken an enormous toll on cities, states and individuals such as Michael Lary and his family, Defendants have realized blockbuster profits. Indeed, upon information and belief, each of the Defendants have experienced material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

CAUSES OF ACTION

COUNT I
FRAUD/FRAUDULENT MISREPRESENTATIONS
(*Against All Defendants*)

162. The Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

163. As alleged herein, Defendants engaged in false representations and concealments of material fact about using opioids for chronic pain.

164. Defendants, individually and acting through their employees and agents, and in concert with each other, made misrepresentations and omission of material fact to physicians and residents in the to induce them to prescribe, administer, fill, purchase, and consume opioids as set forth herein.

165. Defendants knew that their representations and omissions were false.

166. Defendants intended that physicians and individuals would rely upon their misrepresentations and omissions.

167. The physicians and individuals such as Michael Lary reasonably relied on Defendants' misrepresentations and omissions.

168. Defendants intentionally failed to alter or correct the fraudulent information it had disseminated through the United States and the and acted willfully, wantonly, and maliciously.

169. Because of his reliance on Defendants' misrepresentations and omissions of material fact, Michael Lary became addicted and ultimately died as a result of his addiction and Plaintiffs have been damaged.

170. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT II
NEGLIGENCE
(*Against All Defendants*)

171. The Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

172. Manufacturing Defendants have a duty to exercise reasonable care in marketing its opioids to doctors and residents. Manufacturing Defendants have breached their duty by knowingly and fraudulently misrepresenting the benefits of, and downplaying the risks of, opioids for chronic pain.

173. Manufacturing Defendants have used deceitful marketing ploys, KOLs, Front Groups, and other schemes to increase profits at the cost of public health causing an opioid epidemic. Manufacturing Defendants have acted willfully, wantonly, and maliciously.

174. Likewise, Distributor Defendants have a duty to exercise ordinary care in distributing opioids. Distributor Defendants have breached their duty by failing to prevent or reduce the distribution of opioids, or to report the increase in the distribution and/or sale of opioids.

175. Distributor Defendants have intentionally failed to prevent or reduce the distribution of opioids, or to report any increases in the sale of opioids, so that they could increase profits and

receive rebates or kick-backs from Manufacturing Defendants. Distributor Defendants have acted willfully, wantonly, and maliciously.

176. As a proximate result, Manufacturing and Distributor Defendants and its agents have caused Plaintiffs to incur damages.

177. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT III
NEGLIGENCE *PER SE* VIOLATION OF MISS CODE ANN. § 97-23-3
(*Against Manufacturing Defendants*)

178. The Plaintiffs re-allege and incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

179. Mississippi law recognizes the doctrine of negligence per se, which provides that breach of a statute or ordinance may render the offender liable in tort without proof of lack of due care. Violations of statutes and regulations support a cause of action for negligence per se where the plaintiff is within the class protected, the harm sustained is the type sought to be prevented, and that the violations proximately caused the plaintiff's injuries.

180. Miss. Code Ann. § 97-23-3 provides:

> Any person who, with intent to sell or in any way dispose of merchandise, […], or anything offered by such person, directly or indirectly, to the public for sale or distribution, or who, with intent to increase the consumption of or demand for such merchandise, […] or other thing, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or an interest therein, makes, publishes, disseminates, circulates or places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated or placed before the public within the state, in a newspaper or other publication, or in the form of a book, notice, handbill, poster, bill, circular, pamphlet or letter, or by a label affixed to the merchandise or its container, or in any other way, an

> advertisement of any sort regarding merchandise, […] or anything so offered to the public, which advertisement contains any assertion, representation or statement of fact which is untrue, deceptive or misleading, […], and which such person knew, or might on reasonable investigation have ascertained to be untrue, deceptive or misleading[.]shall be guilty of a crime.

Further, violators of Miss. Code Ann. § 97-23-3, "may be held civilly responsible in tort for damages to persons or property proximately resulting from a violation of this section."

181. Defendants' marketing scheme to optimize profits by misrepresenting and falsely touting opioids as the panacea to chronic pain was done intentionally. Defendants violated Miss. Code Ann. § 97-23-3, because they acted knowingly, intentionally and/or unlawfully, by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of themselves or others, attempted to obtain or obtained payment from public funds for services or supplies furnished or purportedly furnished pursuant to § 97-23-3.

182. The Defendants engaged in false and misleading representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain, by misrepresenting the nature of the drugs, and by aggressively promoting them for chronic pain for which they knew the drug were not safe or suitable. These false or misleading statements were made to the public, including to Plaintiff's Community.

183. The Plaintiffs are within the class intended to be protected by the public safety statutes and regulations concerning advertising and controlled substances.

184. Defendants' violations of these public safety laws are prima facie evidence of negligence *per se*.

185. By reason of Defendants' violation of § 97-23-3, Plaintiffs have been damaged.

186. Plaintiffs seek damages for physical and emotional injuries of Michael Lary, for

wrongful death and for all damages available under the law caused by Defendants' actions.

187. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorney fees and costs, and pre- and post-judgment interest.

188. At every stage, Defendants knew or should have known that their conduct would create an unreasonable risk of physical harm to others, Michael Lary and the wrongful death plaintiffs. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT IV
NEGLIGENCE *PER SE*
(*Against All Defendants*)

189. The Plaintiffs incorporate the allegations within all prior paragraphs within this Complaint as if they were fully set forth herein.

190. Federal law mandates require that Defendants must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(a)(1), (b)(1). These federal regulations impose a non-delegable duty upon both manufacturers and distributors to "design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor or manufacturer] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §

1301.74(b).

191. In addition to reporting all suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. Indeed, all flagged orders must be reported.

192. Each Defendant was further required to register with the DEA, pursuant to the federal Controlled Substance Act. Each Defendant is a "registrant" as a wholesale distributor and/or manufacturer in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. By the acts as set forth hereinabove Defendants violated the federal Controlled Substances Act.

193. Defendants violated § 41-29-141 of the Mississippi Uniform Controlled Substances Law, which provides that, "It is unlawful for any person: (2) Who is a registrant under Section 41-29-125 to manufacture a controlled substance not authorized by his registration, or to distribute or dispense a controlled substance not authorized by his registration to another registrant or other authorized person[.]" MS Code § 41-29-141 (2013).

194. Defendants violated § 41-29-139 of the Mississippi Uniform Controlled Substances Law, which provides that, except as authorized by law, "[I]t is unlawful for any person knowingly or intentionally: (1) To sell, barter, transfer, manufacture, distribute, dispense or possess with intent to sell, barter, transfer, manufacture, distribute or dispense, a controlled substance[.]" MS Code § 41-29-139 (2013).

195. Defendants do not qualify for the "authorized by law" exceptions to the Mississippi Uniform Controlled Substances Law violations because Defendants did not comply with the mandatory terms of the licenses issued to them by the Mississippi Board of Pharmacy or with

federal requirements incorporated by reference, as further detailed in this Complaint.

196. Defendants violated MS Code § 97-1-1, by their conspiracy to commit acts injurious to the public health and to accomplish any unlawful purpose, or a lawful purpose by any unlawful means.

197. Michael Lary and Plaintiffs are within the class intended to be protected by the public safety statutes and regulations concerning controlled substances.

198. Defendants' violations of these public safety laws are prima facie evidence of negligence *per se*. Each Defendant had a duty under, inter alia, these laws to maintain effective controls against diversion of prescription opioids and to guard against, prevent, and report suspicious orders of opioids. Defendants breached mandatory, non-delegable legal duties and did not act reasonably under the circumstances.

199. As described above in allegations expressly incorporated herein, Defendants breached their duties to maintain effective controls against diversion of dangerously addictive opioids, including violating public safety statutes and regulations requiring that as wholesale drug distributors, Defendants could only distribute these dangerous drugs under a closed system – a system Defendants were responsible for guarding.

200. As described above in allegations expressly incorporated herein, Defendants' breach of statutory and regulatory duties caused, bears a causal connection with, is and was a substantial factor contributing to, and/or proximately resulted in, harm and damages to Plaintiffs.

201. The injuries and damages sustained are those which the statutes and regulations were designed to prevent.

202. Defendants' violations of the Mississippi statutes and public safety regulations cited herein were and are substantial factors in the injuries and damages sustained.

203. It was foreseeable that Defendants' breaches of statutory and regulatory duties described herein would result in the damages sustained.

204. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT V
CIVIL CONSPIRACY
(Against All Defendants)

205. The Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

206. Defendants engaged in a civil conspiracy with each other and with the co-conspirators identified above who are not parties to this action. Defendants and their non-Defendant co-conspirators combined to accomplish an unlawful end, or alternatively to accomplish a lawful end by unlawful means.

207. As set forth herein, Defendants engaged in a civil conspiracy to create a public nuisance in conjunction with their unlawful marketing, sale, distribution and/or diversion of opioids into the State and into the .

208. As set forth herein, Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in conjunction with their unlawful distribution and diversion of opioids into the State and into the hands of individuals such as Michael Lary.

209. As set forth herein, Defendants engaged in a civil conspiracy to unlawfully divert opioids and create opioid dependence and abuse.

210. Distributor and Manufacturer Defendants unlawfully failed to act to prevent

diversion and failed to monitor for, report and prevent suspicious orders of opioids.

211. The Manufacturer Defendants further unlawfully marketed opioids in furtherance of that conspiracy.

212. Defendants acted tortiously in concert with each other and/or in pursuit of a common design, and/or Defendants knew each other's conduct constituted a breach of their legal duties and provided substantial assistance and/or encouragement in the conduct.

213. Defendants' conspiracy is a continuing conspiracy, and the overt acts performed in compliance with the conspiracy's objective(s) are ongoing.

214. Defendants acted with a common understanding or design to commit unlawful acts, as alleged herein, and acted purposely, without a reasonable or lawful excuse, to create the injuries alleged herein.

215. Defendants acted with malice, purposely, intentionally, unlawfully and without a reasonable or lawful excuse.

216. Plaintiffs have been damaged as a direct and proximate result of this civil conspiracy Defendants' conspiracy and Defendants' actions and omissions in furtherance thereof proximately caused and/or substantially contributed to the direct and foreseeable losses alleged herein.

217. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including, *inter alia*, restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VI
UNJUST ENRICHMENT
(*Against All Defendants*)

218. The Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

219. As an expected and intended result of their conscious wrongdoing as set forth in this Complaint, Defendants have profited and benefited from opioid purchases made by the City and its residents.

220. When individuals like Michael Lary purchased opioids, they expected that Defendants had provided necessary and accurate information regarding those risks. Instead, Defendants had misrepresented the material facts regarding the risks and benefits of opioids.

221. Defendants have been unjustly enriched at the expense of individuals, including decedent. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* restitution, disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants, attorneys' fees and costs, and pre- and post-judgment interest.

COUNT VII
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT ("RICO"), 18 U.S.C. § 1961, ET SEQ.
(*Against All Defendants*)

222. The Plaintiffs re-allege and incorporate by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

223. This claim is brought by the Plaintiffs against each Defendant for actual damages, treble, damages, and equitable relief under 18 U.S.C. §1964 for violations of 18 U.S.C. §1964, et seq. In this matter, the evidence will establish the existence of an enterprise, as defined by law, and that the Defendants each engaged in one of four specified, prohibited relationships between the Defendants and the enterprise. Thus, liability exists on behalf of the named Defendants arising

from their role in the enterprise.

224. The Defendants named in this lawsuit, each and every one, are guilty of violations of the Racketeer Influenced and Corrupt Organization Act, commonly known as the RICO statute. The alleged conduct violated 18 U.S.C. § 1962 (c) or (d).

225. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity . . ." 18 U.S.C. §1962(c).

226. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. §1962(c) and §1962(d). While the roles of the Defendants varied, each engaged in conduct and/or participated in the conduct of the enterprise by having some part in directing the affairs of the enterprise, or otherwise playing a role in the operation or management of the enterprise, or being associated with those who exert control over the enterprise, all to a sufficient degree necessary to give rise to liability under the relevant statute.

227. Each Defendant herein constituted an Enterprise for purposes of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to over-promote, over-sell and over-distribute drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons that obtain prescriptions for them or to be made available for misuse.

228. To accomplish this purpose, the Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the sale and distribution of Defendants' opioids and popularize the misunderstanding that opioids are effective for chronic pain and the risk of addiction is low ("the Scheme").

229. At all relevant times, each Defendant was aware of the Enterprise's conduct, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales, distributions, and prescriptions of opioids. In fact, Front Groups and KOLs received direct payments from Manufacturer Defendants in exchange for their role in the Enterprise, and to advance the Enterprises' fraudulent marketing scheme whereas Distributor Defendants received kick-backs from Manufacturing Defendants if they reached particular monthly goals.

230. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1) marketing, promotion, and advertisement of Defendants' opioid medicines; (2) advocacy at the state and federal level for change in the law governing the use, prescription, and distribution of Defendants' opioids; (3) issuing prescriptions and prescription guidelines for Defendants' opioids; and (4) issuing fees, bills, and statements demanding payment for prescriptions of Defendants' opioids.

231. The persons engaged in the Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by the defendants who manufactured these drugs. The misconduct of the Defendants arose from a common goal of this RICO enterprise, which was to create and grow a market and off-market for opioid prescription drugs even though the proffered uses were not supported by valid scientific or medical evidence.

232. The Enterprise functioned as a continuing unit for the purposes of executing the Scheme and when issues arose during the Scheme, each member of the Enterprise agreed to take actions to hide the Scheme and the existence of the Enterprise. Each of these acts were related to

each other and had continuity, in that the activity or threat of such activity was ongoing and the defendants' efforts to over-promote opioid drugs was constant.

233. Each Defendant participated in the operation and management of the Enterprise by directing its affairs as described herein. The prohibited conduct in which the Defendants engaged had the same purpose – over-promoting opioid prescription drugs and profiting from such; the same results – creating a robust market for these drugs across the county and in the ; the same victims – the citizens of the United States in general and the in particular; and the same methods of commission – pursing an intricate, pervasive marketing plan directed at both healthcare providers and the public to convince them to seek out, prescribe, and use these drugs.

234. While Defendants participated in, and are members of, the Enterprise, they have an existence separate from the Enterprise, including distinct legal statuses, affairs, offices and roles, officers, directors, employees, and individual personhood.

235. Defendants, singularly or in combination with another, orchestrated the affairs of the Enterprise and exerted substantial control over the Enterprise by, at least: (1) making misleading statements about the purported benefits, efficacy, and risks of opioids to doctors, patients, the public, and others, in the form of telephonic and electronic communications, CME programs, medical journals, advertisements, and websites; (2) employing sales representatives or detailers to over-promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data (e.g., IMS data) to coordinate and refine the Scheme; (4) employing doctors to serve as speakers at or attend all-expense paid trips to programs emphasizing the benefits of prescribing opioid medications; (5) funding, controlling, and operating the Front Groups to target doctors, patients, and lawmakers and provide a veneer of legitimacy to the Manufacturer Defendants' Scheme; (6) retaining KOLs to promote the use of their opioid medicines and (7)

concealing the true nature of their relationship with the other members of the Enterprise, including the Front Groups and the KOLs.

236. To carry out, or attempt to carry out, the scheme to defraud, the members of the Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. §1341 (mail fraud) and §1343 (wire fraud).

237. Specifically, the members of the Enterprise have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§1341 and 1343), within the past ten years.

238. The The Enterprise's predicate acts of racketeering (18 U.S.C. §1961(1)) include, but are not limited to:

a) Mail Fraud: The members of the Enterprise violated 18 U.S.C. §1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

b) Wire Fraud: The members of the Enterprise violated 18 U.S.C. §1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

239. These communications were integral to the commission of the torts and wrongs

alleged herein, they constituted a pattern in that they have the same or similar purposes, results, participants, victims, or methods of commission, or otherwise are interrelated by distinguishing characteristics and are not isolated events, and each such communication is a violation of federal and/or state law.

240. This mail and wire transmissions were made in furtherance of Defendants' Scheme and common course of conduct designed to sell drugs that have little or no demonstrated efficacy for chronic pain; increase the prescription rate for opioids; and popularize the misunderstanding that the risk of addiction is low when using opioids.

241. The members of the Enterprise aided and abetted others in violating the law. To achieve their common goals, the members of the Enterprise hid from the and its residents: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioids; and (3) the true nature of the relationship between the members of the Enterprise.

242. Plaintiffs also allege that they have been injured by a conspiracy to violate Section 1962(c), as more fully elucidated in this Complaint, as permitted by Section 1962(d). The Defendants consciously agreed to work together to build the market for opioids, pursuant to which they committed numerous acts of wire and/or mail fraud, all of which was part of a pattern of racketeering activity. The other named Defendants consciously participated in and/or supported this conspiracy.

243. Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their co-conspirators

agreed to conceal their fraudulent scheme.

244. The members of the Enterprise knew, and intended that, Plaintiffs would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

245. Each of the Defendants, to a greater or lesser extent, engaged in wrongful and illegal conduct starting no later than the date of introduction of their various opioid drugs products on the US market and continuing thereafter to the present. The pattern of racketeering activity described herein is currently ongoing and open- ended, and threatens to continue indefinitely unless this court enjoins the racketeering activity.

246. Plaintiffs allege that the coordinated behavior of the named Defendants constituted an enterprise and/or an "association in fact" enterprise, as that term is known under the statute and the case law interpreting the same. This association in fact is not named as a party, but it is an independent entity that maintains a formal or informal structure consisting of actors, including the named defendants and others to potentially be named.

247. This "association in fact" was an enterprise that engaged in a pattern of wrongdoing. The predicate acts, including wire and mail fraud, were a regular way of doing business in interstate commerce for this RICO enterprise.

248. There has been no criminal conviction or charges arising from these events thus far in the . Nonetheless, Mississippi law also prohibits the types of conduct described in this petition. Moreover, certain of the Defendants have either been charged with or admitted to violations of civil or criminal statutes, as described in this complaint.

249. Therefore, whether alleged under the provisions of state or federal law, Plaintiff would show that the named Defendants have, individually and/or jointly, engaged in a pattern of activity that violates the law; or conspired to engage in such behavior; and such behavior took

place across state lines. The primary objective of the enterprise was to sell and profit from the sale of opioid drugs. Hence, Defendants are accountable for all forms of relief available under federal or state law.

250. There is a direct causal relationship between the alleged injuries and the violations of the RICO statute in that the Defendants' marketing, promotional, and business activities arose from predicate acts that actually did serve to achieve the successful sale of the Defendants' opioid prescription drugs. It will be shown that, as a result of the conduct summarized above, Plaintiffs the suffered damages being completely foreseeable to the Defendants and, in fact, a risk calculated by Defendants. Some of the damages that were sustained are described elsewhere in this pleading.

251. As a result of Defendants' racketeering activity, the Plaintiffs have suffered damages.

252. Defendants' violations of 18 U.S.C. §1962(c) and (d) have directly and proximately caused injuries and damages to the Plaintiffs for business and economic losses and specifically for lost wages and wage earning capacity of the decedent and bring this action for three times actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. §1964(c).

WRONGFUL DEATH

253. Plaintiff incorporates herein the allegations in paragraphs 1-252 above as if fully restated herein.

254. The wrongful conduct alleged herein, negligence, actions or inactions, and/or omissions of the Defendants proximately caused Michael Lary's death on December 19, 2016. Plaintiffs plead this cause of action under Mississippi Code Ann. §11-7-13 and seek all damages available under the law for the wrongful death of Michael Lary, including damages for Michael's

physical and emotional pain and suffering, lost wages and wage earning capacity, loss of love and affection and any and all other damages available under the law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, Linda Lary and Lacy Lary of Carroll County, Mississippi respectfully pray:

253. That the acts alleged herein be adjudged and decreed to be unlawful and that the Court enter a judgment declaring them to be so;

254. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, including overpromotion and over-supply of opioids in and around the state of Mississippi and from continuing to violate Mississippi law;

255. That Plaintiffs recover all measures of damages, past, present and future, including disgorgement of profits, compensatory and punitive damages, and all damages allowed by law to be paid by the Defendants and that judgment be entered against Defendants in favor of Plaintiffs;

256. That Defendants be ordered to abate the public nuisance that they created in the state of Mississippi damaging individuals such as Michael Lary and his family.

257. That Plaintiffs be awarded all damages for physical and emotional pain and suffereing, loss of love and affection and any other damages available under Mississippi's wrongful death law, damages proximately caused by Defendants' negligence and gross negligence and punitive damages to punish and deter the Defendants and protect the public safety.

258. That Plaintiffs recover the costs and expenses of suit, pre- and post- judgment interest, and reasonable attorneys' fees as provided by law, and for such other further relief as the Court may deem just and proper.

This the 19th day of December, 2019.

Respectfully submitted,

Linda Lary and Lacy Lary, individually and for the Wrongful Death Beneficiaries of Michael Lary

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